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EXAMINER	
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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,455	MEIR, ROSENBERG	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 37 is objected to because of the following informalities: Applicant fails to set forth the location of the differential pressure sensor in line 5. For the purposes of examination, the Examiner is interpreting the sensor to be disposed within the housing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus- function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out

and distinctly claim the invention as required by the second paragraph of section 112." *See* MPEP § 2181, citing In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

Applicant has failed to set forth what structure is meant by the "means for being...powered" in claims 15-17 and 34-36. Page 6 of applicant's specification provides a disclosure that the device may be powered by RF, acoustic, or optical waves, but discloses no structure capable of carrying out the powering function. Page 4, lines 4-7 of applicant's specification discloses that the apparatus comprises an antenna 28 for wireless communication with an external device, but does not set forth any apparatus that is capable of receiving power to the device. Therefore, the disclosure is not enabling for a "means for being...powered" by the various claimed power sources.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The following guidance is provided to determine whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked:

a. If the corresponding structure, material or acts are described in the specification in specific terms (e.g., an emitter-coupled voltage comparator) and one skilled in the art could identify the structure, material or acts from that

description, then the requirements of 35 U.S.C. 112, second and sixth paragraphs and are satisfied. See Atmel, 198 F.3d at 1382, 53 USPQ2d 1231.

b. If the corresponding structure, material or acts are described in the specification in broad generic terms and the specific details of which are incorporated by reference to another document (e.g., attachment means disclosed in U.S. Patent No. X, which is hereby incorporated by reference, or a comparator as disclosed in the IBM article, which is hereby incorporated by reference), Office personnel must review the description in the specification, without relying on any material from the incorporated document, and apply the "one skilled in the art" analysis to determine whether one skilled in the art could identify the corresponding structure (or material or acts) for performing the recited function to satisfy the definiteness requirement of 35 U.S.C. 112, second paragraph. See Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc., 412 F.3d 1291, 75 USPQ2d 1116 (Fed. Cir. 2005).

7. In the instant case, applicant's recitation of an antenna that communicates with an external device does not sufficiently disclose an apparatus that is capable of being powered by an external source, failing the first test. Applicant did not disclose the "means for" by incorporating any disclosure by reference, failing the second test. Accordingly, claims 15-17 and 34-36 are considered by the Examiner to be indefinite.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-24, 38-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al.

In the specification and figures, Cowan discloses the device substantially as claimed by applicant. With regard to claims 1, 18, 19, 40, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a second pressure sensor 52 disposed within the housing downstream of the valve, and a CPU or microprocessor associated with element 52 disposed within the housing and connected to the pressure sensor (see FIG 1, columns 3-4).

Cowan discloses a first pressure sensor 54 upstream of the valve 50, but fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the

references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance.

With regard to claims 2-3, 9, the CPU or valve-gauge assembly with processing unit 52 disclosed by Cowan is electrically connected to the pressure sensors (see columns 5-6, FIG 1). The valve-gauge assembly is connected to transmitter 64 that transmits information to an external computing device (see column 6, lines 1-15).

With regard to claims 4, 5, 10, and 14, applicant claims that the CPU comprises a "means for calculating" a particular parameter. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

c. the claim limitations must use the phrase "means for " or "step for; "

d. the "means for " or "step for " must be modified by functional language; and

e. the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure... described in the specification and equivalents thereof." See MPEP 2181(II). In paragraph 0008 of US 2004/0260229, applicant discloses that the CPU compares values generated by the pressure sensors to generate a differential pressure. It is the position of the Examiner that this disclosure indicates that the "means for calculating" comprises a programmed algorithm. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26). Such programs are considered by the Examiner to be functional equivalents of the algorithm disclosed by applicant, since differential pressure values are known in the art to control valve movement. Accordingly, the disclosure of Cowan suggests the apparatus of applicant's claims 4, 5, 10, and 14.

With regard to claims 6-8, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that

disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claims 15-17, applicant claims that the CPU comprises a "means for calculating" a particular parameter. In the interest of compact prosecution, Examiner is addressing the claims on their merits, despite the 35 USC 112 rejections presented above. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

a. the claim limitations must use the phrase "means for " or "step for; "

b. the "means for " or "step for " must be modified by functional language; and

c. the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure... described in the specification and equivalents thereof." Page 4, lines 4-7 of applicant's specification discloses that the apparatus comprises an antenna 28 for wireless communication with an external device. Cowan discloses that his apparatus comprises a transmitter 64 for communicating with an external receiver, which the Examiner considers to be a functional equivalent to applicant's antenna. Accordingly, claims are unpatentable over the prior art.

With regard to claim 20, Cowan and Meisel fail to disclose that the CPU is located outside the housing 24. It has been held that mere rearrangement of the parts of a device found in the prior art is within the skill of a worker in the art, especially if the device with the instantly claimed arrangement would not perform differently than the prior art device. See MPEP 2144.04(IV)(B). In the instant case, applicant has not stated that the location of the CPU outside the housing is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the CPU does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

With regard to claims 21, 24, 38, and 39, Cowan discloses a first pressure sensor 54 upstream of the valve 50. Cowan also discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or

closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance using the programmed CPU and wireless communication disclosed by Cowan.

With regard to claims 22-23, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an

external device (see column 6, lines 1-15). Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claims 41-44 and 46, Cowan and Miesel suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by

applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

10. Claims 25-30 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman.

In the specification and figures, Cowan discloses the apparatus and method substantially as claimed by applicant. With regard to claim 25, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a pressure sensor 52 disposed within the housing downstream of the valve, and a microprocessor associated with element 52 disposed within the housing and connected to the pressure sensor (see FIG 1, columns 3-4).

Cowan fails to disclose that the pressure sensor 52 comprises a differential pressure sensor. However, Cosman discloses an implantable differential pressure sensor that upon undergoing a conformational change, transmits that information to an external device. The device allows for the accurate measurement of a difference in pressure across a membrane (see columns 1-2). The combination of the shunt apparatus disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

With regard to claim 26, both Cowan and Cosman disclose that the apparatus is connected to an apparatus that transmits information to an external computing device (see Cowan column 6, lines 1-15, Cosman column 1, lines 13-24).

With regard to claims 27-30, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claims 34-36, applicant claims that the CPU comprises a "means for calculating" a particular parameter. In the interest of compact prosecution, Examiner is addressing the claims on their merits, despite the 35 USC 112 rejections presented above. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

d. the claim limitations must use the phrase "means for " or "step for; "

e. the "means for " or "step for " must be modified by functional language; and

f. the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure... described in the specification and equivalents thereof." Page 4, lines 4-7 of applicant's

specification discloses that the apparatus comprises an antenna 28 for wireless communication with an external device. Cowan discloses that his apparatus comprises a transmitter 64 for communicating with an external receiver, which the Examiner considers to be a functional equivalent to applicant's antenna. Accordingly, claims are unpatentable over the prior art.

With regard to claim 37, Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressure sensors and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). The combination of the method disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system and method that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

11. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in in view of US 4,206,762 to Cosman, further in view of US 6,428,080 to Miesel.

In the specification and figures, Cowan and Cosman suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of an

additional pressure sensor located on a second catheter. With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32.

However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in the apparatus suggested by Cowan and Cosman in order to diagnose blockages throughout the system.

Response to Arguments

9. Applicant's arguments filed 19 September 2007 in the Appeal Brief have been entered and fully considered.

10. Applicant's arguments with respect to the rejection(s) of the pending claim(s) under 35 USC 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. Furthermore, the finality of the Office action mailed 16 March 2006 is withdrawn. This is a non-final action on the merits of the claims.

12. Upon further consideration of the claims, a new ground(s) of rejection is made over Cowan, Meisel, and Cosman as presented above.

13. Applicant's arguments with regard to the 35 USC 112 rejections of claims 15-17 and 34-36 have been fully considered but they are not persuasive.

Applicant argues that the "means for being non-invasively powered" is set forth in the specification as antenna 28. However, page 4, lines 4-7 of applicant's specification discloses that the apparatus comprises an antenna 28 for wireless communication with an external device. Communication with an external device does *not* necessarily include receiving power from an external device, which requires some sort of power storage apparatus. Applicant's specification does not set forth any apparatus that is capable of receiving power to the device. Page 6 of applicant's specification provides a disclosure that the device may be powered by RF, acoustic, or optical waves, but discloses no structure capable of carrying out the powering function. Therefore, the disclosure is not enabling for a "means for being...powered" by the various claimed power sources, and the claims are indefinite.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
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Art Unit 3761
28 November 2007